CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
REGULATORY AFFAIRS

1615 H STREET, N.W.
WASHINGTON, D.C. 20062
(202) 463-5457

June 14, 2002

Ms. Evangeline Tsibris Cummings
U.S. Environmental Protection Agency
Office of Environmental Information
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA Docket NO. OEI-10014

Dear Ms. Cummings:

These comments are filed on behalf of the U.S. Chamber of Commerce ("U.S. Chamber"), the world's largest business federation, representing more than three million businesses of every size, sector, and region. The U.S. Chamber is pleased to have this opportunity to provide comments on the U.S. Environmental Protection Agency's ("EPA" or "the Agency") Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

The U.S. Chamber applauds EPA for the transparent process it has used to create and receive comment upon the Agency's guidelines. Both the online comment session (in which the U.S. Chamber participated) and the May 15, 2002, public meeting were unique among federal agencies. Both efforts are appreciated, and both efforts will no doubt help to ensure that EPA's final guidelines will reflect the concerns of the communities regulated or otherwise affected by agency information.

The U.S. Chamber has long supported the common sense use of high-quality data by federal agencies in their development of policies and regulations. It is inherently true that better data leads to better policy. Therefore, the U.S. Chamber strongly supported the Data Quality Act[1] (the Act) when it was passed as Section 515(a) of the Fiscal Year 2001 Treasury and General Government Appropriations Act. The U.S. Chamber was also an active participant as the Office of Management and Budget developed the government-wide guidelines mandated by the Act (OMB Guidelines).[2]

---

[1] Pub. L. No. 106-554

[2] Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." 67 FR 8452 (February 22, 2002).

The U.S. Chamber believes that the final version of the OMB Guidelines accurately and comprehensively implements the intent of the Data Quality Act. The U.S. Chamber further applauds OMB for recognizing that individual agencies have particular needs and concerns relating to data quality, and that further agency guidelines are therefore warranted. Nevertheless, this process raises concerns that agencies will create data quality guidelines that are inconsistent with or in some manner diminish the quality requirements established by Congress and OMB. In some respects, as discussed below, EPA's Draft Guidelines validate such concerns.

The U.S. Chamber appreciates the difficulty EPA has faced in creating information quality guidelines that are sufficiently broad to cover the varied program offices within the Agency, yet sufficiently specific to provide adequate guidance on how those program offices should implement the Agency's – and OMB's – information quality standards. Unfortunately, EPA's Draft Guidelines consistently err on the side of too much generality.

According to OMB's directive, federal agency guidelines are required to "explain" how such guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by the agency. A common problem throughout EPA's guidelines, however, is a lack of detail and specificity in this explanation. The degree of flexibility permitted by the guidelines has the potential to eviscerate the protections intended to be afforded by the Data Quality Act and the OMB Guidelines.

Instances of EPA's lack of specificity abound throughout the Draft Guidelines. As just one such example, EPA states that it "may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints or resources."[3] This type of poorly defined "case-by-case" approach is inconsistent with OMB's mandate and is inconsistent with the principles behind the data quality law. Where exceptions are allowed, they should be narrow and well defined. This is true with regard to a myriad of "case-by-case" or similar provisions contained in the Draft Guidelines, each of which is discussed separately below. Unless and until such provisions are revised to contain greater detail and guidance, the U.S. Chamber believes that the Agency's guidelines will not properly implement the data quality law and that, accordingly, OMB has proper cause to reject the proposed guidelines.

Because of the many issues that arise in each of the various sections of the Draft Guidelines, the U.S. Chamber's comments closely track the organization of the proposal. For ease of review, the headings used below are the same as those set forth in the Draft Guidelines.

---

[3] Draft Guidelines, Lines 761-762 (hereafter "Lines ___-___").

I. Overview, Scope and Applicability

Section 1.1: What is the purpose of these guidelines?

The Agency's proclivity to defer decisions and to provide excessive discretion to program offices and regions is prominently on display in the first section of the Draft Guidelines. The Draft Guidelines state that they "may not apply to a particular situation based on the circumstances, and EPA retains discretion to adopt approaches on a case-by-case basis that differ from the guidelines, where appropriate."[4] This statement begs several questions. For instance, what constitutes a "particular situation" that makes it "appropriate" for the Agency to bypass the guidelines? Who will make such a "case-by-case" determination? At what point in time will such a determination be made? What assurances can EPA provide that the approaches to be adopted will be, to the fullest extent possible, consistent with the OMB Guidelines?

Certainly, circumstances will arise where dissemination of information will be necessitated prior to completion of all mandated quality checks, such as in times of national emergency. But such circumstances should, to the best of EPA's ability, be expressly spelled out in the guidelines. A blanket statement such as the one quoted above does little more than provide cover to those who would seek to avoid compliance with the Data Quality Act. The U.S. Chamber recommends that this broad language be removed from the guidelines and that all exceptions to the guidelines be set forth with reasonable specificity.

While it is vital to adequately delineate the scope of the guidelines, it is perhaps even more important that the guidelines be fully enforceable. EPA's Draft Guidelines take a step in the wrong direction by stating that the guidelines "are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on EPA or the public."[5] EPA's guidelines implement the Data Quality Act. They therefore constitute rules, rather than guidance, and are legally enforceable. The U.S. Chamber encourages the Agency to recognize this fact and to remove any alternative suggestion from the guidelines. But, regardless of whether EPA does so, the U.S. Chamber notes that the issue of judicial review will ultimately be decided by the courts. EPA's pronouncements are simply not determinative.[6]

---

[4] Lines 404-406.
[5] Lines 402-403.
[6] *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C.Cir. 2000).

Section 1.2: When do these guidelines apply?

The U.S. Chamber generally applauds EPA's approach with regard to when the quality guidelines are to be applied. However, the Agency again provides a broad, poorly defined exclusion to the general rule. To the point, the draft guidelines state that factors "such as imminent threats to public health or homeland security, statutory or court-ordered deadlines, *or other time constraints*, may limit or preclude applicability of these guidelines."[7]

Such "other time constraints" should either be set forth with specificity or defined in a highly limited manner, clearly providing that the exception applies to only the most extraordinary circumstances. The need to meet the standards set forth in the guidelines, as well as to address correction requests, will almost always present time constraint concerns, as these requirements will often be labor intensive. But this fact alone is not sufficient reason for EPA to fail to fully comply with the data quality requirements. EPA's guidelines should more clearly state this fact.

Section 1.3: What is not covered by these guidelines?

This section of the Draft Guidelines includes two distinct definitions, "information" and "dissemination," both of which are central to the determination of whether Agency data will be required to meet the standards set forth in the final guidelines. The Agency seeks to define "information" by listing three items not considered to constitute "information." The first two of these, opinions and mere references or links to other sources of information, do not generally present concerns. The third exclusion, however, is overly broad, poorly defined, and should therefore be modified or withdrawn.

The third exclusion states that the Agency "may identify other materials that are not 'information' for purposes of these guidelines." This raises a series of questions that the final guidelines must address. What standards are to be applied when identifying materials as something other than information? Who is to make such a decision? When is the decision to be made? Will the decision itself be disseminated? EPA must provide considerably more guidance and answer these questions if this provision is to amount to anything more than an open invitation to program offices to disregard the data quality requirements.

[7] Lines 418-420 (emphasis added).

Meanwhile, EPA's discussion of "dissemination" contains ten separate bullet points setting forth circumstances where the guidelines would not apply to information released or distributed by the Agency because such information is deemed not to be "disseminated." Generally, the U.S. Chamber finds that these exclusions are consistent with the OMB Guidelines. However, certain of the exclusions are incomplete, creating possible ambiguity.

For instance, the exclusion for distribution of information in correspondence with individuals or persons[8] is, in our view, overly broad. Often, the Agency is aware that information it is providing in correspondence with "persons" – defined to include associations, corporations, and other entities – is intended for wider distribution. The Agency's guidelines should reflect this fact, in part by adopting the approach used in the Draft Guidelines with regard to distribution of information by grantees or contractors. That is, if the Agency "sponsors" the further distribution of information by a recipient of correspondence, the data quality guidelines should apply.[9] In the context of this particular exclusion, however, the U.S. Chamber recommends that the term "sponsor" be expanded to include further distribution by a recipient when the Agency knows or has reason to know of the further distribution at the time of the Agency's initial distribution to the person. For instance, EPA is aware that trade associations generally distribute Agency letters, opinions, etc. to their members. Thus, such information provided to trade associations should be subject to the data quality requirements.

Another exclusion of concern is the exclusion for information distributed in press releases.[10] In this regard, the U.S. Chamber recognizes that EPA's Draft Guidelines are consistent with an exclusion provided for by the OMB Guidelines. However, where a press release is the exclusive means of dissemination of information that otherwise would be subject to the data quality law, the U.S. Chamber believes that the quality requirements should apply. We therefore recommend that this exclusion be modified accordingly.

The next exclusion that the U.S. Chamber believes should be modified is that for adjudicative processes.[11] While OMB authorizes this exclusion, it has not defined "adjudicative processes." EPA, on the other hand, has done so in a very broad fashion by excluding:

---

[8] Lines 474-481.

[9] In lines 440-442, the Draft Guidelines provide that distribution by outside parties is not, generally, considered to be "sponsored" by EPA unless it "is using the outside party to disseminate information on the Agency's behalf." The U.S. Chamber believes this principle should apply equally to all third parties.

[10] Lines 482-485.

[11] Lines 528-544.

> "Distribution of information in documents related to any formal or informal administrative action determining the rights and liabilities of specific parties, including documents that provide the findings, determinations or basis for such actions. Examples include the processing or adjudication of applications for a permit, license, registration, waiver, exemption, or claim; actions to determine the liability of parties under applicable statutes or regulations; and determination and implementation of remedies to address such liability."[12]

The U.S. Chamber believes this definition is overly broad and thereby excludes various categories of information that should be subject to the data quality guidelines. We therefore recommend that the Agency limit this definition to formal adjudicative proceedings as governed by the Administrative Procedure Act.[13] Furthermore, the use of the term "related to" is similarly overbroad. The exclusion should be limited to documents or information created specifically for the adjudicative proceeding and should not include documents that merely became part of the record in such a proceeding.

Finally, EPA has included a catch-all exclusion that threatens to unreasonably restrict the entire scope of the Agency's quality guidelines. The Draft Guidelines provide that "EPA may identify other instances where information is not 'disseminated' by EPA because EPA does not initiate or sponsor the distribution of information."[14] How will EPA do so? Who will make this determination, and when? Can such a determination properly be made on a case-by-case basis? The U.S. Chamber recommends that this catch-all exclusion be removed from the final guidelines, and that to the extent EPA believes further exclusions are warranted, such further exclusions be made subject to notice and comment before being included in the Agency's guidelines. Without such protections, the determination of what constitutes "dissemination" is tentative and ambiguous and therefore of little assistance to EPA's offices and regions.

---

[12] Lines 534-544.
[13] 5 U.S.C. § 554.
[14] Lines 545-546.

Section 1.4: What happens if information is initially not covered by these guidelines, but EPA subsequently disseminates it to the public?

The U.S. Chamber applauds EPA for recognizing that the status of information can change over time and that previously excluded information which is subsequently "disseminated" must comply with the data quality standards. However, we believe one simple clarification should be made to this provision.

The Draft Guidelines state that the quality standards are to apply to subsequently distributed information when EPA "adopts, endorses or uses the information to formulate or support a regulation, guidance, or other Agency decision or position."[15] This approach is too narrow. The guidelines should apply to information subsequently "disseminated," regardless of how it is used. As currently drafted, information that initially falls under an exclusion would thereafter acquire a new status where mere dissemination would not bring it within the guidelines' requirements. There is no basis for this distinction. All disseminated information should be governed by the guidelines, regardless of whether it was previously distributed in a manner not covered by the guidelines.

II. Defining Information Quality

Section 2.1: What is "quality" according to the guidelines?

EPA's proposed definitions of quality, utility, integrity and objectivity, as set forth in this section, are consistent with those contained within the OMB Guidelines. The U.S. Chamber therefore recommends against any alteration of this section of the Draft Guidelines. Definitions alone, however, provide little direction to program and region offices seeking to comply with the guidelines. Therefore, with regard to the requirements of "utility" and "integrity" – which are not discussed elsewhere in the Draft Guidelines – EPA should provide further instruction as to how these standards are to be met. For example, if EPA intends to rely on existing practices to meet the standards, those existing practices should be explicitly set out. Otherwise, EPA should set forth the processes to be used by Agency offices to meet the standards.

[15] Lines 549-551.

III. Ensuring and Maximizing Information Quality

Section 3.1: How does EPA ensure and maximize the quality of disseminated information?

In the Draft Guidelines, the Agency states that it will ensure and maximize the quality of information "by using policies and procedures well established within the Agency as appropriate to the information product."[16] This approach causes some concern.

There is certainly logic in proposing that the Agency incorporate the new data quality requirements into existing quality processes. But an important distinction must be recognized between existing procedures and existing quality standards. The U.S. Chamber believes that the Agency's existing procedures have not consistently led to information products that would meet the new quality standards. Thus, while it may be efficient to build upon existing procedures, the Agency's final guidelines should explicitly recognize that existing practices do not necessarily result in an adequate standard of quality, and that the new quality standard must be met regardless of the procedures used to meet it.

Section 3.2: How does EPA define influential information for these guidelines?

As defined in the OMB Guidelines, information is "influential" if an agency "can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on *important public policies or important private sector decisions*."[17] OMB authorizes agencies to further define the term "in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible."[18] Accordingly, any refinement of the term should be limited to that which is necessitated by the unique nature of EPA's responsibilities.

It is vital to note that OMB's definition of influential information focuses on both public policy and private sector impacts. EPA's Draft Guidelines, on the other hand, focus primarily on the public policy effects of the information. This is an oversight that should be remedied in the final guidelines.

---

[16] Lines 581-582.
[17] OMB Guidelines, Sec. V.9 (emphasis added).
[18] OMB Guidelines, Sec. V.9.

Of the four categories of information that are considered "influential" under the Draft Guidelines, only one addresses the private sector impacts of disseminated information. But that category is limited to information disseminated in support of "economically significant" actions under Executive Order 12866.[19] There is no rational basis to limit "important private sector decisions" to this relatively small number of information disseminations. The U.S. Chamber opposes any arbitrary monetary limits placed on this definition. The question should be whether important private sector decisions are being affected regardless of the monetary value of such decisions. "Important" does not automatically equate to economically large. A small industry may suffer a numerically small impact from bad data that could nevertheless decimate the industry. A different example is EPA's prior proposal to require public access to "worst case scenario" data under the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act, which would not have had an immediate $100 million impact. But the use of such information by terrorists would potentially have a devastating effect on both the entire industry and individual businesses. Nevertheless, under EPA's proposed definition, such data would likely not be subject to the heightened standard to be applied to influential information.

Moreover, the fact that the term "economically significant" is defined to include both a $100 million limit and a separate narrative description is of little practical assistance. In practical terms, any specific dollar amount included in the guidelines is going to artificially be used as a cutoff by those applying the guidelines to particular data. Therefore, the U.S. Chamber recommends that EPA adopt a narrative description to describe information that has an impact on important private sector decisions, without adopting any particular dollar limit. Specifically, the U.S. Chamber recommends that EPA adopt as a definition of "influential" Executive Order 12866's definition of "significant regulatory action," with the exception of the provision setting forth the $100 million threshold.[20]

---

[19] "Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

[20] Specifically, the proposed definition would include agency actions that are likely to:

(1) Adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(1) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(1) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(1) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

The three other categories of "influential" information present additional concerns:

Information disseminated in support of top Agency actions that demand the ongoing involvement of the Administrator's office and extensive cross-agency involvement: Beyond the narrowness of the definition lies an immense practical problem. How, when, and by whom will the determination of "top Agency actions" be made? EPA instructs its offices and regions to incorporate the information quality principles into pre-dissemination review procedures. But unless the individual developing the information is prescient enough to know the future involvement of the Administrator's office, this standard cannot practically be applied in time for proper pre-dissemination review. The U.S. Chamber supports the principle behind this category, but recommends that it be revised to address these practical concerns.

Work Products Undergoing Peer Review: The U.S. Chamber agrees that such work products should always be deemed influential.

Case-by-case: Here, again, EPA has left too much discretion for the guidelines to have their intended authority and effect. Although the U.S. Chamber understands that not all information can be classified in the general guidelines, EPA should provide specific instruction to its offices and regions concerning how to determine, on a case-by-case basis, whether information is "influential."

Section 3.3: How does EPA ensure and maximize the quality of "influential" information?

As EPA correctly states, the OMB Guidelines require a high degree of transparency of data and methods to facilitate the reproducibility of "influential" scientific, financial, or statistical data. The U.S. Chamber applauds EPA's description of four factors necessary to ensure such transparency: (1) the source of the data used, (2) the various assumptions employed, (3) the analytical methods applied, and (4) the statistical procedures employed.[21] Transparency of all data relating to these four factors will help ensure that reproducibility can be adequately tested. But the U.S. Chamber encourages the Agency to expand these factors to include identification and characterization of data gaps and uncertainties to ensure even greater transparency of influential information.

[21] Lines 633-635.

EPA's proposed approach to the subject of reproducibility raises additional concerns. The Draft Guidelines discuss the impact of the unavailability of data because of privacy, trade secret, intellectual property, or confidentiality concerns. EPA's Draft Guidelines, however, provide no direction as to how the Agency will determine when such concerns are present and/or whether the concerns exist to an extent such that full transparency cannot occur. The final guidelines should provide further instruction to program and region offices on how to make this determination.[22]

A related U.S. Chamber concern is EPA's approach to "robustness checks." The OMB Guidelines require agencies to conduct "especially rigorous robustness checks to analytic results" when confidentiality concerns do not allow the otherwise requisite level of public access to data and methods. EPA's Draft Guidelines merely provide that, in such circumstances, the Agency "should to the extent practicable, apply robustness checks to analytic results and document what checks were taken."[23] Requiring documentation of robustness checks that have been taken is a positive step, and the U.S. Chamber therefore encourages the Agency to retain such a provision in the final guidelines. However, two other weaknesses of the "robustness checks" provision should be remedied.

First, what does EPA mean by "to the extent practicable?" Who makes this judgment? If the Agency presently believes that certain circumstances may prevent the completion of robustness checks, it ought to specifically spell out those circumstances where such checks will not be mandatory. The current standard leaves far too much discretion and contains far too much ambiguity in this regard.

Second, the Agency should provide considerably more detail regarding the conduct of robustness checks. As the Draft Guidelines currently stand, program offices and regions are left with no guidance whatsoever as to how the checks should be conducted. In drafting better instructions, the Agency should bear in mind OMB's charge that, where public access will not occur due to confidentiality constraints, agencies must apply "*especially rigorous* robustness checks."[24] EPA's draft standard fails to meet the Agency's obligation in this regard.[25]

---

[22] EPA's use of third-party data, and in particular proprietary third-party data, presents other problems. This topic is discussed below in Section 3.5.
[23] Lines 639-640.
[24] OMB Guidelines, Sec. V.3.b.ii.B.ii (emphasis added).
[25] Further discussion of the robustness check issue is contained in the discussion of third party data (Section 3.5).

Section 3.4: How does EPA ensure and maximize the quality of "influential" scientific risk assessment information?

For human health, safety and environmental risk assessments, the OMB Guidelines require agencies to either adopt or adapt standards set forth in the Safe Drinking Water Act (SDWA) Amendments of 1996. EPA has adopted a two-pronged approach to this requirement.

For health-related risk assessments, EPA proposes adapting the SDWA standards. For environmental and safety-related risk assessments, EPA has completely deferred a decision as to whether and how to adopt or adapt these principles. As a preliminary matter, the U.S. Chamber notes that any agency seeking to adapt, rather than adopt, the SDWA standards, should be capable of articulating, and must in fact articulate, the reason. EPA has failed to do so, either for human health risk assessments, where the Agency proposes a substitute standard, or for environmental and safety-related risk assessments, where it does not. Accordingly, EPA should either make a far more compelling case for adaptation or should simply adopt the SDWA Amendments in their entirety for all three types of risk assessments addressed by OMB's Guidelines.

As to the proposed adaptation for human health risk assessments, the only apparent modification to the SDWA provisions is the inclusion of the phrase "as appropriate" in setting forth when the best available, peer-reviewed science must be used. EPA's approach, once again, begs the question: When is it "inappropriate" to use the best available, peer-reviewed science? Without a clarification of this point, the decision whether to comply with this element of the guidelines is left entirely to the program office. The OMB Guidelines do not support a voluntary approach to adoption or adaptation of the SDWA Amendments provisions, nor should EPA's own guidelines.

EPA's reasoning for the proposed adaptation with regard to human health risk assessments, as best can be determined from the preamble discussion, is based on "EPA's experience with the SDWA principles, existing policies in place at EPA, and the applicability and appropriateness of the SDWA language with regards to the variety of risk assessments conducted by the Agency."[26] EPA does not, however, explain how adding the term "as appropriate" does anything other than provide unguided discretion to those within the Agency having responsibility for ensuring compliance with the information quality guidelines. It thus appears that EPA's "experience" with the SDWA amendments has been that their mandatory nature is a burden disliked by the Agency. This is inadequate justification for adapting, rather than adopting, the SDWA amendments for human health risk assessments.

Another vital modification proposed by the Agency, and opposed by the U.S. Chamber, is EPA's statement that the term "best available," when referring to the SDWA's required use of "the best available, peer-reviewed science," refers to availability at the time an assessment is made rather than at the time of dissemination. This modification of the standard is contrary to the principles of the data quality law and the OMB Guidelines, in that it fails to ensure the dissemination of information that is timely and that thus remains valid. The U.S. Chamber therefore strongly encourages EPA to modify this provision to provide that the term "best available" refers to the time EPA disseminates a risk assessment, or other information derived from such an assessment, rather than the time the risk assessment was made. The U.S. Chamber does not propose, however, that the Agency be required to put risk assessments on hold while waiting for developing data. Rather, EPA should merely be certain that, at the time risk assessments are disseminated or used, all existing data has been considered.

Lastly, the Draft Guidelines fail to provide any clue as to whether and how the Agency plans to adopt or adapt the Safe Drinking Water Act amendments as relating to environmental and safety related risk assessments. Although the Agency asks for stakeholder and scientific input on this question, EPA's failure to provide at least a draft adaptation of the SDWA provisions as relating to *environmental* risk assessments is of great concern. Environmental risk assessments go to the very heart of EPA's mission. The Agency states that it intends to seek input from stakeholders and the scientific community on this issue, but does not state how or when. While the U.S. Chamber recognizes that information quality guidelines will evolve over time, we believe EPA should adopt the SDWA amendments without change until such time as further study and analysis suggests that an adaptation would be appropriate and consistent with the principles contained in the data quality law.

---

[26] Lines 277-281.

Section 3.5: Does EPA ensure and maximize the quality of information from external sources?

EPA properly recognizes that third-party information comes in many forms, over which the Agency has varying levels of control. However, regardless of the source of information, EPA should consistently apply one simple standard: All information disseminated by the agency, regardless of original source, should comply with the data quality law, the OMB Guidelines, and the Agency guidelines.

The Draft Guidelines identify four categories of data providers: contractors, grantees, the regulated community, and voluntary submitters. The U.S. Chamber believes these categories are both accurate and useful.

Contractors: EPA often hires Contractors for the very purpose of providing scientific or statistical data. As EPA recognizes, it is this group over which the Agency has the greatest control.[27] Because of the nature of the work often performed by Agency contractors, this category of data providers presents particular concerns with regard to Agency compliance with the new data quality standards.

As stated, the U.S. Chamber begins with the premise that the Agency should apply the same high quality standards to all information it disseminates, regardless of whether that information originated with a third party. Neither the data quality law nor the OMB Guidelines suggest that a lower standard should or can be applied to third party data. The data provided by contractors, however, may often present an additional concern.

Among the four categories of data providers, contractors are the most likely to attempt to claim a proprietary privilege for models or data used in developing an information product to be provided to EPA. As discussed, the OMB Guidelines, as well as the EPA Draft Guidelines, contain a requirement of reproducibility for influential scientific, financial and statistical information that is disseminated by the Agency. This is typically achieved through transparency of data, research design, and methods. However, information subject to ethical, feasibility, or confidentiality constraints, such as a proprietary claim, is generally excused from the transparency requirement.

[27] Lines 321-324.

The U.S. Chamber has serious concerns regarding the scope of this exclusion. Without limitations, the exclusion would permit third party data providers to unilaterally place large amounts of information off limits to the public, merely by asserting that such information is proprietary in nature. Worse yet, proprietary claims have the potential to place large amounts of information off limits even to EPA itself. But compliance with the data quality standards simply cannot be assured without access to underlying models, data, methods, etc. As such, the Agency's use of proprietary information conflicts with the goals and intent of the data quality law.

For this reason, the U.S. Chamber proposes that EPA modify its information quality guidelines to provide that information subject to third party proprietary claims be used only in extraordinary circumstances. Generally, EPA should require that all models, methods, designs and data created or used by contractors in connection with the provision of an information product be publicly disclosed. Proprietary protections should be allowed only when an information product is not otherwise available or attainable. This approach will ensure that, whenever possible, the public will have the greatest opportunity to test reproducibility.

In the rare circumstance where proprietary third party information must be used, the U.S. Chamber encourages the Agency to utilize particularly vigorous robustness checks.[28] Where robustness checks are required because of a third party proprietary claim, the U.S. Chamber urges EPA to subject analytic results to what amounts to an "internal peer review." Specifically, we believe the Agency's Science Advisory Board (SAB) should be required to review and confirm, on the record, the quality of analytic results reached by contractors using proprietary models. In so doing, it is essential that the SAB have access to the proprietary models, even though public access will not occur, as results cannot adequately be tested without access to the models used to reach such results. Of course, the proprietary models would retain all confidentiality protections throughout and following the SAB review.

[28] As discussed, the OMB Guidelines require vigorous robustness checks where public access to data and methods will not occur due to other compelling interests, such as confidentiality.

The proposed SAB review should examine all assumptions and the quality of data used to reach all findings, as well as the soundness of conclusions and results drawn from the use of the proprietary model. The review should include, but not be limited to, an examination of: assumptions; methodologies; statistical analyses; sources, types, and levels of uncertainty; data sources; and associated reviews of such data sources. Following the review, the SAB should either accept or reject the contractor's analytic results and be required to provide a written rationale for its decision. This rationale should, to the extent consistent with the proprietary protections afforded to the subject model, be disseminated along with the influential information containing or relying upon the analytic results.

While the U.S. Chamber strongly encourages EPA to adopt such an SAB "peer review" as one robustness check, we do not believe robustness checks should be limited to this review. To the contrary, the U.S. Chamber recommends that EPA adopt, in the final guidelines, a number of robustness checks that can assist in confirming the quality of information provided by third party contractors and subsequently disseminated by EPA.

Grantees: Grantees present a similar situation to that of contractors, in that grantees may desire to disallow public access to information they have developed. For instance, grantees may have concerns regarding intellectual property rights that, if exercised, could interfere with full transparency.

Fortunately, the data access law, also known as the "Shelby Amendment,"[29] has already guaranteed public access to much of the research data used by grantees. But the data access law requires an affirmative act on the part of one seeking the information (i.e., a Freedom of Information Act request), while the data quality law places the onus upon an agency to disseminate underlying data and methods.

The U.S. Chamber proposes that information developed by grantees and subsequently used by EPA be treated in the same fashion as proposed for contractor data. That is, EPA should not use grantee data for which models or underlying data cannot be made fully transparent, unless such information is unavailable or unattainable from other sources. In circumstances where such information is otherwise unavailable or unattainable, analytical results should be subject to an SAB peer review and other robustness checks as described above.

[29] Pub. L. No. 105-277.

Regulated Community: As for information provided by the regulated community under a statute, regulation, permit, order or other mandate, EPA has a distinct type of control. Such information is generally provided with a guarantee of authenticity, given that providing false information under such circumstances is a crime.[30] Further, as EPA discusses in the preamble to the Draft Guidelines, the Agency ensures the quality of such information through steps such as requiring samples to be analyzed by specific procedures and by certified laboratories.[31]

Nevertheless, it should not be forgotten that information provided by the regulated community as required by law is not intended, by the provider, for EPA dissemination. If such information is subsequently "disseminated" by the Agency, the Agency should establish and follow additional procedures, if and as necessary, that allow EPA to adequately assure the information's quality without further burden to the provider.

It should also be noted that voluntary submissions are often made in connection with information provided by the regulated community. For instance, interest groups often provide EPA with information in an effort to defeat a particular permit application. Such information should not be treated with the same deference as the regulated community's information, the accuracy of which is subject to penalty, but should instead be treated the same as all other voluntary submissions.

Voluntary Submissions: Finally, information voluntarily provided to EPA – whether through comments to proposed rules, studies or otherwise – offers little protection in the way of quality checks. However, such information is likely to be provided to the Agency for the purpose of influencing the Agency, and it is therefore in the provider's best interest to meet high quality standards. The U.S. Chamber applauds EPA's promise to work with voluntary providers and others to establish and publish factors that the Agency would use to assess the quality of this type of information, and the U.S. Chamber would welcome guidance from the Agency regarding how we can improve the quality of the information we provide to the Agency.

[30] 18 U.S.C. §1001.
[31] Lines 334-336.

The Agency's approach to this issue seems highly reasonable, and the U.S. Chamber looks forward to further dialogue on the matter. We do, however, offer the precautionary note that the U.S. Chamber will strongly oppose any effort to impose gatekeeper criteria that would prevent voluntarily submitted information from even being reviewed by the Agency. There is no compelling reason to *require* specific quality standards of voluntarily submitted information unless EPA plans to disseminate the data or to use it as a basis for otherwise disseminated information.

IV. Pre-dissemination Review

Section 4.1: What are the administrative mechanisms for pre-dissemination reviews?

The OMB Guidelines stress the importance of pre-dissemination review: "As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information."[32]

EPA, on the other hand, virtually glosses over this requirement by providing only that EPA offices should incorporate the new data quality principles "into their existing pre-dissemination review procedures as appropriate," and allowing unique and new procedures "as needed."[33] There are several problems with this approach.

First, this section continues the recurring theme of providing too little instruction and too much flexibility to EPA offices and regions. EPA should state unequivocally, as did OMB, that pre-dissemination review is an absolute requirement. Such review is not to be done "as appropriate" or "as needed." It is always appropriate and always needed, and the Agency's guidelines should reflect this fact.

[32] OMB Guidelines, Sec.III.2.
[33] Lines 698-700.

Second, as previously discussed, EPA's existing procedures are not adequate unless pre-dissemination review is a mandatory aspect of those procedures. EPA should not merely rely upon its existing structure to meet this vital component of the data quality law.

Third, the Agency provides no direction as to the manner in which pre-dissemination review is to be conducted. At least one other agency has provided a good model, which the U.S. Chamber believes should be followed or closely adapted by EPA. The Department of Transportation (DOT) sets forth seven minimum procedural steps designed to ensure adequate pre-dissemination review:

1) Allow adequate time for reviews, and consult with stakeholders;
2) Verify compliance with the information quality guidelines;
3) Indicate whether information is "influential";
4) Ensure that information fulfills the stated intentions and that conclusions are consistent with the evidence;
5) Indicate the origin of data;
6) For information products subject to the quality guidelines, include a notice so stating at the time of dissemination;
7) Ensure that each program office can provide additional data on the subject matter of any covered information it disseminates.

Regardless of whether EPA adopts these specific steps, the Agency must, along with reinforcing the fact that pre-dissemination review is required and not optional, establish some procedure to be followed by EPA programs and regions to ensure proper quality review at every stage of the development of information.

V. Correction of Information

Section 5.1: What are EPA's administrative mechanisms for affected persons to seek and obtain appropriate correction of information?

The U.S. Chamber approves of EPA's decision to house the administrative correction process in the Office of Environmental Information (OEI), a centralized office. Although we have serious concerns regarding certain details of the correction process, the active involvement of OEI will offer the best opportunity for an objective process and result.

Section 5.2: Who may request a correction of information from the Agency?

EPA's Draft Guidelines define an "affected person" as one "who may benefit or be harmed by the disseminated information." The U.S. Chamber believes this definition should be retained in the final guidelines.

Section 5.3: What should be included in a request for correction of information?

The U.S. Chamber appreciates the need for EPA to obtain sufficient information in order to evaluate a correction request and approves of the Draft Guidelines in this regard. However, we believe EPA should include an additional requirement that a person seeking correction include information explaining how they are an "affected person." Without this information, EPA cannot properly evaluate whether the person is sufficiently "affected." By requiring this information in the original request for correction, EPA will limit arbitrary decision making on the question of whether the person is in fact sufficiently affected.

Section 5.4: Will EPA consider all requests for correction of information?

EPA sets forth three categories of correction requests that the Agency will not review. The first and third of these – frivolous requests and requests from non-affected persons – are reasonable and the U.S. Chamber has no objection to their inclusion in the final guidelines. The second category, however, presents one of the areas of greatest concern in the Draft Guidelines.

In the second category, EPA seeks to entirely exclude from the complaint process those requests that pertain to EPA actions "where a mechanism by which to submit comments to the Agency is already provided."[34] Most importantly, this would disallow all requests relating to information contained in or supporting a proposed regulation. There are several problems with this exclusion.

Most fundamentally, neither the OMB guidelines nor the Data Quality Act itself supports EPA's approach. While the OMB Guidelines and the Act do not specifically address rulemaking, neither do they permit a blanket exclusion from the complaint process for rulemaking proceedings. In the U.S. Chamber's view, ensuring the quality of data is rarely, if ever, more important than when data is used in a proposed or final regulation. Excluding the rulemaking process from such a vital part of the data quality law – an affected party's right to seek correction – undercuts the very purpose of the law.

[34] Lines 737-738.

EPA's approach to this issue attempts to equate an affected party's rights under the data quality law with those available under Administrative Procedure Act (APA) rulemaking. But the complaint mechanism set forth in the data quality law and the OMB Guidelines includes several important elements and protections that are not present in the rulemaking process. For instance, the OMB Guidelines require agencies to establish timelines for decisions on correction requests – timelines that do not generally exist under APA rulemakings.[35] In fact, as the Agency is well aware, regulations often take years to progress to the final rule stage. Conversely, requests for correction should almost always be resolved in a matter of weeks. There is no justifiable reason for the Agency to grant itself this extra time to correct errors contained in proposed rules, particularly given the important role data plays in proposed EPA regulations.

A separate protection afforded by the data quality law and the OMB Guidelines, but missing from the rulemaking process, is the right to an administrative appeal. Given the importance of data relied upon by an agency in a proposed rule, it would be to the benefit of both the Agency and the regulated community to allow for an administrative review – and a final agency determination – of the quality of such information at the earliest possible time.

EPA's Approach Effectively Eliminates Any Right for a Party to Seek Review of Incorrect Information in a Rulemaking. The data quality law, unlike an APA rulemaking, allows a correction request relating to a specific data item on the basis that the data does not meet the quality standards set by the EPA and/or OMB Guidelines. EPA seeks to protect its guidelines from being judicially enforced, stating that the guidelines "are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on EPA or the public."[36] Thus, the Agency takes the position that affected parties have no legal rights to enforce the guidelines in court. At the same time, the Agency excludes rulemaking proceedings from the data quality correction process. EPA cannot have it both ways. The Data Quality Act and the OMB Guidelines mandate the right to seek correction without limitation as to how the data has been used. EPA must recognize this fact and remove the rulemaking exclusion from the correction request process.

[35] As discussed below, EPA has failed to comply with this requirement in its Draft Guidelines.
[36] Lines 402-403.

Section 5.5: How will EPA respond to a request for correction of information?

EPA's proposed process for responding to correction requests contains an exception that could virtually swallow the rule. EPA provides that it "may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources."[37] These incredibly broad exceptions essentially provide EPA programs and regions with carte blanche power to take no action in response to even the most egregious errors.

The Agency fails to provide any guidance as to what "priorities" will allow the correction process to be ignored. If an information owner determines that a particular regulation is a "priority," does that mean that the Agency can use poor quality data – even fraudulent data – to support the regulation? What "time constraints" will allow EPA to continue to disseminate invalid information? Will program offices be permitted to establish arbitrary deadlines and then ignore correction requests? What does EPA mean by "resources?" Does the Agency intend to balance the cost of correcting information with the cost to the regulated community if bad data is continued to be released and used?

This aspect of the guidelines simply must be changed to comply with the data quality statute. The Data Quality Act provides that affected parties must be permitted to "seek and obtain" correction of information not in compliance with the law. The statute leaves no wiggle room in this regard. EPA's massive exceptions provide far too much flexibility to the Agency and far too little protection to those affected by EPA information. EPA should commit to correcting all information that does not meet the requisite quality standards. Anything less is unacceptable under the law, and, in the U.S. Chamber's opinion, should by itself result in OMB's rejection of the Agency's guidelines.

Section 5.6: Will EPA reconsider its decision on a request for the correction of information?

The U.S. Chamber approves of the information that EPA proposes to require from a person seeking reconsideration of a denial of that person's request for correction. We therefore recommend that this section remain intact in the final agency guidelines.

[37] Lines 761-762.

Section 5.7: How does EPA process requests for reconsideration of EPA decisions?

The U.S. Chamber believes that the formation of a panel to consider correction request appeals is, generally, an appropriate process. But EPA's approach contains a fundamental problem, in that the program office Assistant Administrator should not be the final arbiter of the appeal.

It is important that those personnel charged with conducting reviews of correction requests and appeals be objective. The U.S. Chamber has serious concerns about the ability of EPA program offices to be entirely objective with regard to information developed or relied upon by that office. While it is appropriate for the Assistant Administrator of an office to be a member of a panel reviewing a request, the final arbiter should be from outside the particular program office. The U.S. Chamber therefore recommends that the EPA Chief Information Officer be charged with making the final decision on any appeal.

Additional Issues Relating to the Correction Request Process:

Deadlines for Agency Decisions: The OMB Guidelines unequivocally state that: "Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information."[38] EPA has failed to do so.

The U.S. Chamber recommends that EPA adopt a 45-day review period for both stages of correction requests, i.e., the original request and the request for reconsideration. We recognize that some challenges may involve complex and controversial data that may require additional time. Therefore, the U.S. Chamber would not oppose guideline language permitting an additional 45-day extension under such circumstances, so long as notice and the factual basis for the extension are provided to the affected party seeking correction or reconsideration before expiration of the original 45-day period.

Deadlines for Correction Requests: During the May 15, 2002, public meeting, there was considerable discussion of establishing a deadline for the submission of correction requests. Essentially, the deadline would act as a "statute of limitations" that would arbitrarily cut off an affected person's right to seek correction. The U.S. Chamber strongly opposes any such deadline.

[38] OMB Guidelines, Sec. III.3.i.

The establishment of a deadline would undercut EPA's stated commitment to ensure that information "is, and remains, as accurate and credible as possible."[39] Those who would propose a deadline raise a legitimate concern regarding the amount of resources necessary to address a dated correction request. But an arbitrary deadline is not the answer to this concern. Rather, EPA already has an effective "cutoff" in that, under the Draft Guidelines, only "affected persons" may seek correction of information. As discussed, "affected persons" are those "who may benefit or be harmed by the disseminated information."[40] This forward-looking definition ensures that only information with the future potential to benefit or harm a person can be considered for correction. If the information no longer has the potential to benefit or harm, the person seeking correction will not be deemed "affected" and will therefore not have "standing" to seek correction.

By utilizing the definition of "affected person" to create a flexible cutoff, EPA can ensure that bad information will be corrected as long as it continues to have an actual impact. At the same time, EPA will not be required to use valuable resources on the correction of purely outdated information. And, of course, the Agency will always retain the option of correcting outdated information, even if a non-affected (or no longer affected) person brings the error to EPA's attention.

Public Notice of Correction Request: The Draft Guidelines establish no procedure to notify the public either when a correction has been sought or when a correction has been made. The U.S. Chamber believes this omission should be rectified in the final agency guidelines.

When an affected person makes a correction request, EPA is formally placed on notice that an error may exist in information that the Agency has disseminated. The Agency's final guidelines should mandate that program offices and regions take steps to notify the public that the information has been challenged. Given that information is disseminated in a variety of ways, EPA should be flexible in establishing a system of notification. The U.S. Chamber suggests a two-pronged approach.

[39] Lines 175-176.
[40] Lines 715-716.

First, any information that is posted on the Agency's website should be "tagged" in some manner, with a clear indication that the quality of the information has been challenged and that the challenge is under review. Second, EPA should create a unique web page on which all data under challenge is identified. These steps will best assure that the public has notice of the potential that information is not of sufficient quality. The public in turn can continue to use the information at its own discretion.

Further, when a correction to information is made pursuant to a challenge, the U.S. Chamber believes that the correction itself should be disseminated in the same manner and to the same degree as was the original information. Merely removing the information from the Agency's website or other public access is insufficient, a fact that the final guidelines should clearly explain.

The U.S. Chamber appreciates the opportunity to submit these comments and thanks the Agency for considering the views of the U.S. business community on this most important subject.

Sincerely,

William L. Kovacs